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September 25, 2015

Via Email Only

Hon. Jed S. Rakoff
Room 1340
United States Courthouse
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Docket as defendands letter brief.

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Re: JDS Therapeutics, LLC et al., v. CVS Pharmacy, Inc., (S.D.N.Y.) Case No. 1:15-cv-04365-JSR-AJP

Dear Judge Rakoff:

Pursuant to instructions received from chambers, Defendant CVS Pharmacy, Inc. ("CVS") submits this letter brief in support of its motion to compel Plaintiffs JDS Therapeutics, LLC and Nutrition 21, LLC ("Plaintiffs") to produce documents regarding the testing (including pre-Complaint testing) of CVS's products that are accused of patent infringement. Plaintiffs have refused to provide a privilege log of testing documents that are being withheld on attorney client privilege or work product grounds or even to disclose whether any testing has occurred. Plaintiffs also contend that they can withhold testing of CVS products—testing that is essential to proving Plaintiffs' infringement claims—until the service of their expert reports on November 20, 2015. Plaintiffs' position is inconsistent with the rules and case law concerning the assertion of privilege over testing data that will be used to prove patent infringement, and would result in great prejudice to CVS. As an initial matter, under Fed.R.Civ. P. 26(b)(5), Plaintiffs must identify any material they seek to withhold. Moreover, those documents that reflect the facts of the results of testing of CVS's products are not protected by attorney work product. And, even if they were, in this case CVS has a substantial need for these documents now in order to prepare its defense. The asserted claims of the '772 patent family (3 of the 5 patents-in-suit) require that the products contain nicotinic acid. None of the accused products have nicotinic acid as an ingredient; all of those products contain niacinamide. This Court's rulings in the Pfizer case made plain that the only way that Plaintiffs could assert literal infringement of the '772 patent family for products that use niacinamide would be to test the accused products for the presence of some nicotinic acid. Because Plaintiffs must rely on testing of CVS's products to prove literal infringement, the withholding of testing data concerning CVS's products until expert discovery is nothing more than an effort to prevent CVS from having a



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reasonable opportunity to conduct fact discovery surrounding that testing. Therefore CVS requests that this Court compel the production of any testing prior to expert discovery.

I. Background

Although the present motion arises in the context of Plaintiffs' responses to CVS's First Set of Requests for Production of Documents and Things (Nos. 1-94) and CVS's First Set of Interrogatories (Nos. 1-20), the dispute is part of CVS's ongoing effort to ascertain the scope of the claims that Plaintiffs actually intend to pursue in this lawsuit so that it can efficiently conduct both fact and expert discovery within the schedule set by this Court. As this Court may recall, Plaintiffs brought suit in this Court against Pfizer in Case No. 12-cv-9002, alleging infringement of all five of the patents asserted in the present litigation, plus an additional patent. The case proceeded to the eve of trial, with Plaintiffs eventually dropping all but the claims of a single patent (the '301 patent). That narrowing was likely due in no small part to this Court's rulings on Pfizer's motion for summary judgment of non-infringement. In its decision, this Court concluded that "niacinamide is not the same as nicotinic acid, and therefore the presence of niacinamide in Centrum® products cannot serve as the basis for" literal infringement of the three "'772 related patents" (all of which are asserted here). Order at p. 3 (Dkt. 136).² This Court also found that "the combination of chromium picolinate and biotin in Centrum® does not produce a synergistic or greater than additive effect," and therefore the '480 patent, also asserted here, was not infringed. Id. Plaintiffs included none of these four patents in the Joint Pretrial Order in the *Pfizer* case. (Dkt. 148).

Despite this Court's rulings, Plaintiffs brought suit alleging infringement based on CVS's "private label products" that "cop[y] the ingredients and dosages of the active ingredients used in Centrum® multivitamins." First Amend. Compl. at ¶26 (Dkt. 15). Plaintiffs alleged literal infringement of the '772 patent family, even though none of the accused products contain nicotinic acid (based on their labels and product specifications). CVS therefore wrote to Plaintiffs on July 22, 2015, to ascertain whether Plaintiffs were in fact proceeding with claims of literal infringement of

¹ The dispute encompasses several different discovery responses, but Document Request Nos. 5, 6, and 7, and Plaintiffs' responses, are illustrative. *First*, CVS requested documents regarding "tests, measurements, evaluations, studies, analyses or experiments conducted by or on behalf of Plaintiffs related to the Accused Products." Plaintiffs objected that the request was "premature" and "expect[ed]" that any analyses "will be the subjects of expert reports." *Second*, CVS requested documents regarding "any pre-filing investigation conducted by You relating to the infringement allegations contained in the Complaint." Plaintiffs refused to provide any documents, objecting on among other grounds, attorney-client and work product privilege. *Third*, CVS requested documents regarding "any testing of any CVS products," but Plaintiffs indicated that they would only produce documents "[t]o the extent this Request seeks documents that are subject to expert reports and supporting documentation."

² The ruling excepted a single product, Centrum® Silver® Adults 50+, due to testing which created a "genuine dispute as to whether that product contains nicotinic acid."



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the '772 patent family and infringement of the '480 patent. Receiving no response, CVS served the discovery requests at issue here on July 31, 2015. After additional requests for a response to the July 22 letter, counsel for Plaintiffs responded on August 11 that Plaintiffs intended to take discovery "on all patents" and on August 13 said that "if [CVS] has information to show that CVS's products do not infringe our patents, then bring that to our attention." Plaintiffs served their infringement contentions on August 24, 2015, alleging "infringement" of all five patents – without indicating whether they were pursuing literal infringement, infringement under the doctrine of equivalents or both. When CVS again wrote to Plaintiffs in an effort to understand whether Plaintiffs were in fact pursuing literal infringement of the '772 patent family and infringement of the '480 patent, Plaintiffs failed to respond.

Plaintiffs' assertion of claims requiring the presence of nicotinic acid highlighted the need to obtain Plaintiffs' testing and analysis supporting such assertions. CVS therefore requested a meet and confer to discuss Plaintiffs' objections to CVS's discovery responses three business days after receiving Plaintiffs' responses. Although the parties were able to come to agreement on several issues, Plaintiffs confirmed that they would not be producing any testing or analyses of the CVS products prior to service of expert reports on November 20, 2015 and would not provide a privilege log of withheld materials. CVS then contacted the Court, leading to this letter brief.

II. Testing of CVS Products is Not Protected and CVS Has a Substantial Need for the Requested Documents

First, Plaintiffs have improperly refused to comply with Rule 26(b)(5), which requires the party claiming that information is "privileged or subject to protection as trial-preparation" to "expressly make the claim" and "describe the nature of the documents . . . in a manner that . . . will enable other parties to assess the claim." Plaintiffs will not even state if any testing has occurred to date, let alone provide a basis for refusing production. Even the cases relied on by Plaintiffs note that privilege logs had been provided. See Sloan Valve Co. v. Zurn Industr., No. 10-204, 2012 WL 5499412, at *2 n.3 (N.D. Ill. Nov. 13, 2012) (plaintiff had agreed to "log the privileged materials in a privilege log"); Sicurelli v. Jeneric/Pentron Inc., No. 03-cv-4934, 2006 WL 1329709, at *2 (E.D.N.Y. May 16, 2006) (finding work product doctrine applied after "review of plaintiffs' privilege log"). CVS is forced to guess as to what might be withheld and the alleged grounds for doing so. For that reason, as to any testing-related documents that are withheld on privilege grounds, CVS therefore seeks the production of a privilege log complying with Rule 26(b)(5).

Second, the documents CVS seeks are not protected by the work product doctrine. Testing data of CVS's products are just that—data—and are therefore not attorney "work product" or mental impressions under Rule 26(b)(3). Shared Memory Graphics LLC v. Apple, Inc., 812 F. Supp. 2d 1022, 1026 n. 4 (N.D. Cal. 2010) (noting "[f]acts are not protected by the work product doctrine" and requiring the production of the underlying basis for infringement contentions under the local rules). Plaintiffs should produce whatever underlying data they have, and appropriately describe that material which they contend is protected (such as material that contains both test data and attorney mental impressions relating thereto) under Rule 26(b)(5).

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Third, even if any testing were considered work product, production is still warranted where, as here, that testing is necessary to establish Plaintiffs' infringement allegations. The Seventh Circuit's analysis of the importance of such discovery in the context of reviewing a dismissal for failure to comply with discovery orders, and an award of attorneys' fees, is instructive. See Loctite Corp. v. FelPro, Inc., 667 F.2d 577 (7th Cir. 1981). The Loctite court began by noting that the claims at issue specified "a series of ingredients and the quantities of these ingredients which must be present." Id. at 579. On appeal, the plaintiff argued that it should not have had to produce testing to support its infringement position, as the district court twice ordered. The Court of Appeals disagreed, explaining that "[i]n a chemical patent, there is no way to show that these elements exist in the accused product without utilizing highly technical tests performed by experts" and as a result "the production of the test results was not only relevant, but essential to the case." Id. at 582. The same circumstances exist here. Plaintiffs' testing is "essential" to their claims, particular those calling for nicotinic acid. They cannot "shelter" their production under the guise of privilege. Id.

Numerous decisions are in accord. For example, in Arthrex, Inc. v. Parcus Medical LLC, No. 11-cv-694, 2012 WL 3778981, at *4 (M.D. Fla. Aug. 31, 2012), the court similarly explained that "[w]hile attorney impressions are not discoverable, the factual basis including documents and actions looked into by the Plaintiff in its pre-litigation investigation are discoverable because the Plaintiff is required to provide a factual basis for their claims." The court therefore ordered the plaintiff to produce documents that were not properly categorized as privileged and provide a log of those it contended still were. Id. at *4-*5. Similarly, in AM Int'l, Inc. v. Eastman Kodak Co., No. 80-c-4016, 1982 WL 171002 (N.D. Ill. Oct. 25, 1982), the court concluded that "if a test has been made concerning a product which plaintiff claims is relevant to the patents at issue, it is part of discovery and defendants are entitled to access to the reports of that test." Id. at *4; see also View Eng'g, Inc. v. Robotic Vision Sys., 208 F.3d 981, 986 (Fed. Cir. 2000) (stating, in the context of Rule 11, that "the patent holder, if challenged, must be prepared to demonstrate to both the court and the alleged infringer exactly why it believed before filing the claim that it had a reasonable chance of proving infringement"); compare Reckitt Benckiser LLC v. Amneal Pharm., LLC, No. 11-6609, 2012 WL 2871061, at *7 (D.N.J. July 12, 2012) (denying disclosure of testing procedures because defendant had not "made testing parameters a central issue"). The above cases illustrate that CVS's need for Plaintiffs' testing outweighs any claim for protection.

Fourth, CVS has a substantial need for Plaintiffs' testing documents and that information is unavailable from another source. See Rule 26(b)(3). Plaintiffs' infringement allegations, and specifically those requiring the presence of nicotinic acid, must be supported by evidence that the accused products contain nicotinic acid. This Court has already determined that this is so. And yet the tables and the specification sheets for the accused products do not contain nicotinic acid as an ingredient, and CVS is unaware of any information indicating otherwise. The court in Tillotson Corp. v. Shijiazhaung Hongray Plastic Products, Lt., 244 F.R.D. 683 (N.D. Ga. 2007), explained why, for example, it is not sufficient to state that CVS could conduct its own testing. If, as in Tillotson, CVS were to conduct its own testing to confirm "that no facts existed to support an infringement claim, the parties would be in the exact same position as they are now and this case



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would then presumably proceed with neither party understanding the basis for the other party's contentions." Id. at 693 (ordering plaintiff to produce testing done in anticipation of litigation no later than 20 days after the order if it wanted to rely on that information at any point in the litigation). CVS needs to understand the basis for the allegations against it, including the testing necessary to support Plaintiffs' claims. And as only Plaintiffs know the facts that establish their claims, CVS cannot get that information from another source.

Fifth, Plaintiffs want to invoke the protections afforded a non-testifying expert under Rule 26(b)(4)(D) as an absolute bar on the production of any information regarding testing data until they disclose that information with their testifying expert report on November 20, 2015. As described above, Plaintiffs' testing and analyses of CVS products will be central to Plaintiffs' claims and, therefore, will unquestionably have to be relied on by a testifying expert. Thus, the third parties that are used to develop the facts on which Plaintiffs' testifying experts will rely at trial cannot be shielded from discovery under 26(b)(4)(D).

The schedule in this case, though, does not provide time for the necessary discovery of third party testing entities between opening expert reports on November 20, 2015, and the responsive reports on December 17, 2015. CVS will need to examine in detail the basis and parameters of any testing Plaintiffs' rely upon through discovery, presumably with a third party subpoena, including a deposition of the relevant individuals involved in the testing. Compare Fast Memory Erase, LLC v. Spansion, Inc., No. 08-cv-0977, 2009 WL 4884091, at *2 (N.D. Tex. Dec. 16, 2009) (relied on by Plaintiffs) (noting that "defendants will be entitled to obtain discovery of any documents, data, or communications disclosed to and considered by the testifying expert" and therefore not requiring production). This necessary, and detailed discovery, will not be possible in the window allocated for expert discovery. Nor are CVS's concerns hypothetical. In the Pfizer litigation, the testing that showed the alleged presence of nicotinic acid in a single product was not completed until the day before the initial expert reports were served. The deposition of the individual that conducted the testing did not occur until after the rebuttal expert report was served. And at that deposition, Plaintiffs' counsel instructed the witness not to answer any questions regarding other accused products that may have been tested. See, e.g., Xie Dep. at p. 16-20 (Oct. 9, 2013). Litigation is not a shell game. Plaintiffs should not be permitted to strategically assert and then waive the work product privilege to sandbag CVS with testing data so late in the discovery process that CVS's ability to analyze the problems with that testing is compromised.

For the above reasons, CVS asks that this Court compel Plaintiffs to produce a privilege log and any testing documents concerning CVS's products that are accused of infringement or be barred from later relying on such testing to establish its infringement claims.

Respectfully submitted,

cc: Counsel of record